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DANN DORFMAN HERRELL AND SKILLMAN  
A PROFESSIONAL CORPORATION  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

EXAMINER

ELHILO, EISA B

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/088,432  
Filing Date: May 31, 2002  
Appellant(s): KLEEN ET AL.

**MAILED**

APR 06 2006

**GROUP 1700**

\_\_\_\_\_  
Stephen D. Harper  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed on April 28, 2005 and refilled on February 2, 2006  
and also in response to the supplemental brief filed on June 10, 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The copending Application No. 10/088,247 filed March 15, 2002 (Examiner's answer mailed on December 15, 2005).

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

US 6,274,364 B1	Bernard et al.	8-2001
US 6,051,033	McDevitt et al.	4-2000

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 13, 15-20 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernard et al. (US 6,274,364 B1). This rejection is set forth in the previous office action, mailed on March 9, 2004.

Claims 14, 21-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernard et al. (US 6,274,364 B1) in view of McDevitt et al. (US 6,051,033). This rejection is set forth in the previous office action, mailed on March 9, 2004.

Claims 28-31 are allowed for the reasons set forth in the previous office action, mailed on November 3, 2004

Bernard (US' 364 B1) teaches a composition formulated as restructuring or setting lotions for hair (see col. 8, lines 15-20). The composition comprises a transglutaminase enzyme (see col. 6, lines 52-60) and at least one substance having substrate activity for the enzyme such as protein hydrolyzates, amino acid and plant extract (see col. 9, lines 17-22), active substance having substrate activity on the carbonyl group of a glutamine residue and of the amino group of a lysine residue (see col. 6, lines 55-57) and casein (see col. 13, line 30).

Although Bernard et al, (US' 364) teaches a hair treating composition comprising transglutaminase enzymes and substance having substrate activity such as protein hydrolyze and casein, the reference does not require such a treating composition with sufficient specificity to constitute anticipation.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply such a composition to the keratin fibers by using such a method,

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because such a composition that comprises transglutaminase enzymes and substance having substrate activity of protein hydrolyze falls within the scope of those taught by Bernard et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success, because such a composition is expressly suggested by Bernard et al disclosure and therefore is an obvious formulation.

Claims 14, 21-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernard et al. (US 6,274,364 B1) in view of McDevitt et al. (US 6,051,033).

The disclosure of Bernard (US' 364 B1) as summarized above, teaches a hair treating composition comprising calcium –dependent transglutaminase enzymes and substance having substrate activity of protein hydrolyze. Bernard et al., does not teach or disclose calcium-independent transglutaminase enzymes as claimed. Bernard et al, also does not teach that the composition can be applied to the hair simultaneously or successively for a limited time as claimed.

McDevitt (US' 033) in analogous art of hair treating formulations, teaches a method for treating wool fibers or animal hair comprising applying to the hair an aqueous solution that comprises a proteolytic enzyme and a transglutaminase which includes both calcium-dependent and calcium-independent transglutaminase (see col. 2, lines 24-28 and col. 7, lines 26-30), and, thus, McDevitt et al, clearly teaches the equivalency between calcium –dependent transglutaminase and calcium –independent transglutaminase which are both used in the same utility. It is also taught by McDevitt et al., that the enzymatic treatments can take place either as stand-alone steps or in combination with other treatments wherein the animal hair material is subjected to treatment with a transglutaminase either subsequent to or preferably simultaneously

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with a proteolytic enzyme treatment and wherein the enzymatic treatment steps are preferably carried out for a duration of at least 1 minute and less than 150 minutes (see col. 5, lines 13-28). It is further taught by McDevitt et al., that the method provides advantages with regard to improved shrink-resistance, and/or improvements of softness and handle are highly desired by the end-user, while minimizing fiber damage relative to existing degradative treatments of wool and other animal hair materials (see col. 2, lines 15-22).

Therefore, in view of teaching of the secondary reference of McDevitt et al., one having ordinary skill in the art would be motivated to modify the composition of Bernard by replacing the calcium –dependent transglutaminase with the calcium –independent transglutaminase as taught by McDevitt and to utilize such a method to apply to the hair the enzymatic composition simultaneously or successively for limited time. Such modification would be obvious because one would expect that the use of calcium –independent transglutaminase simultaneously or successively for limited time as taught by McDevitt would similarly be useful and applicable to the analogous treating composition taught by the primary reference of Bernard et al.

#### **(10) Response to Argument**

The examiner has reviewed Appellant's arguments and respectfully disagrees with counsel's allegations. Specifically, appellants argue that the examiner has not demonstrated that claims 13, 15-20 and 24-26 are unpatentable for obviousness under 35 U.S.C. 103(a) over the Bernard et al. (US' 364 B1) reference that teaches and discloses a newly isolated protease that finds use in promoting desquamation and therefore, appellant cannot understand how applying a desquamating agent to remove undesirable excess skin renders the presently claimed invention obvious as a worker of ordinary skill in the art concerning with developing an improved process

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for restructuring keratin fibers would have had no reason to look to the teaching of Bernard reference for guidance in this endeavor.

The examiner position is such that the arguments are not found persuasive because of the following reasons.

In establishing a *prima facie* case of obviousness, three criteria must be met. See *in re Vaeck*, 947 F.2d. 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (see MPEP 2143).

In this case the three criteria have been met, because all references are in the same analogous art of keratin fibers treating formulation.

Bernard (US' 364 B1) teaches a composition formulated as a hair (keratin fibers) setting or restructuring lotions and lotion or gel against hair loss (see col. 8, lines 15-24). The composition comprises transglutaminase enzymes (protease activator) (see col. 6, lines 553-54 and col. 7, lines 16-22) and hydrophilic active agents (active substances) such as proteins or protein hydrolysates (hydrolyzates), amino acid and plant extract (see col. 9, lines 17-22).

Therefore, there is a sufficient motivation to one having ordinary skill in the art to be motivated to apply the transglutaminase enzymes with the hydrophilic active agents to keratin fibers (hair) as claimed in claim 13 with a reasonable expectation of success for setting and restructuring hair as taught by Bernard et al. (US' 364 B1).

Farther, the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. “*In re Heck*, 699 F.2d 1331, 1332-33 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Iemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Furthermore, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed.Cir.), *cert. denied*, 493 U.S. 975 (1989).

Furthermore, the examiner’s position is that the rejection of the claims over US 6,274,364 B1 is proper because the examiner construed the claim’s language in its broadest reasonable interpretation and wherein the claimed process is preferred to carry out in a single stage and in a preferred embodiment of the invention, the two components are mixed immediately before application which is the broadest interpretation as recited in the specification page 5, lines 3-8, and, thus, the claims are not subject to any limitations as asserted by the appellants (see specification page 4, last paragraph).

With respect to claims 15 and 16, Appellants argue that the examiner has provided no motivation or suggestion to select the protein hydrolyzates in the Bernard’s reference that teaches the protein hydrolyzates as protease activators.

The examiner’s position is such that the arguments are not found persuasive because Bernard et al. (US’ 364 B1) teaches and discloses that the composition may contain other hydrophilic active agents, such as proteins or protein hydrolysates (see col. 9, lines 17-18) which are differ from the specific protein hydrolysates of cysteine that taught by Bernard et al. (US’



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364 B1) in col. 6, lines 35-43. Therefore, there is a clear and sufficient motivation to incorporate protein or protein hydrolysates as the active materials in a formulation that used for setting and restructuring hair as taught by Bernard et al. (US' 364 B1).

With respect to claim 17, Appellants argue that the examiner has provided no motivation or suggestion for selecting these particular substrates of transglutaminase and there is no mention of combining casein with transglutaminase.

The examiner's position is such that the arguments are not found persuasive because Bernard et al. (US' 364 B1) teaches and discloses that protein and protein hydrolysates as the active agents are used in the cosmetic composition (see col. 9, lines 17-18). Bernard et al. (US' 364 B1) also teaches that casein (protein) is perfect superimposed for hydrolysis of the specific peptide substrate (see col. 13, lines 28-31). Therefore, there is a clear and sufficient motivation to incorporate the protein casein as a perfect and superimposed protein hydrolysate in the formulation that used for setting and restructuring hair as taught by Bernard et al. (US' 364 B1).

With respect to claims 18, 19 and 20, Appellants argue that the examiner has provided no motivation or suggestion for selecting particular substrates of transglutaminase that functionalized with an  $\text{H}_2\text{N-R}$  group,  $\text{H}_2\text{N}(\text{CO})\text{-R'}$  group as claimed in claim 18,  $\text{H}_2\text{N}(\text{CH}_2)_4$  group as claimed in claim 19 or  $\text{H}_2\text{N}(\text{CO})\text{-CH}_2\text{-CH}_2$  group as claimed in claim 20. Appellants also argue that the examiner has failed to point out where in the Bernard reference a teaching or suggestion to utilize substrates bearing this type of synthetically functionalized groups may be found.

The examiner's position is such that the arguments are not found persuasive because Bernard et al. (US' 364 B1) teaches and discloses active substances having substrate activity on

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the carbonyl group of the glutamine residue and of the amine group of a lysine residue (see col. 6, lines 52-57) wherein the carbonyl group of the glutamine residue and the amine group of the lysine residue are similar to those described in the appellant's specification at page 4, lines 6-8). Therefore, there is a clear and sufficient motivation to incorporate these active substrates with the carbonyl and amine groups with the transglutamines in a formulation that used for setting and restructuring hair as taught by Bernard et al. (US' 364 B1).

With respect to claims 24, 25 and 26, Appellants argue that there is no prima facie case of obviousness has been established against independent claims 24, 25 or 26 because Bernard reference neither discloses, teaches nor suggests the claimed process.

The examiner's position is such that the arguments are not found persuasive for the same reasons mentioned above.

The examiner also has reviewed Appellant's arguments and respectfully disagrees with counsel's allegations. Specifically, appellants argue that the examiner has not demonstrated that claims 14, 21-23 and 27 are rejected under 35 U.S.C. 103(a) over the Bernard et al. (US' 364 B1) in view of McDevitt et al. (US' 033).

The examiner's position is such that the arguments are not found persuasive because the disclosure of Bernard (US' 364 B1) as summarized above, teaches a formulation for restructuring and setting hair (keratin fibers) comprising calcium -dependent transglutaminase enzymes and substance having substrate activity of protein hydrolyze (see col. 6, lines 52-54).

McDevitt et al. (US' 033) in analogous art of keratin fibers treating formulation, teaches a method comprising contacting, the wool, wool fibers or animal hair with a proteolytic enzyme either preceding or, preferably, simultaneously with transglutaminases that include both calcium-

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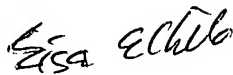
dependent transglutaminase and calcium-independent transglutaminase as claimed in claims 14, 21-22 and 27(see col. 2, lines 23-28, col. 7, lines 25-30), wherein the enzymatic treatment steps are preferably carried out for a duration of at least 1 minute and less than 150 minutes which covered the claimed limitation as claimed in claim 23 (see col. 5, lines 13-28), and wherein the method results in improved characteristics of hair (see abstract). Therefore, there is a clear and sufficient motivation to one having ordinary skill in the art to combine the teachings of references to arrive at the claimed invention with a reasonable expectation of success for improving the characteristic of hair by reducing the fibers damage (restructuring) and improving the hair strength.

Accordingly, the Office maintains that the Examiner has met the burden to establish the prima facie showing of obviousness. Viewed as a whole, the invention as claimed would have been obvious to one of ordinary skill in the art at the time of the invention.

Finally, the Examiner request that this Board when viewing the evidence as a whole, and lacking any secondary indicia of nonobviousness, affirm the decision of the Examiner in whole.

For the above reasons, it is believed that the rejections should be sustained.

Eisa Elhilo (Primary Examiner)  
March 31, 2006



Respectfully submitted

Conferees  
Douglas McGinty (SPE 1751)



Mr. Robert Warden (SPE)

HENKEL CORPORATION  
THE TRIAD, SUITE 200  
2200 RENAISSANCE BLVD.  
GULPH MILLS, PA 19406

APPEAL CONFEEE

